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REMARKS

Claims 1-116 have been canceled and new claims 117-156 have been added. Claims 117-156 are pending.

I. Claim Objections

The Examiner has objected to the amendments to the claims that were filed with Applicants' response on October 6, 2003, alleging that they introduce new matter. Specifically, the Examiner states that, "The added material which is not supported by the original disclosure is as follows: the independent claims for example, claim 17 recite 'wherein said protein stimulates the proliferation of myeloid cells' and there is no support for this in the instant specification." *See* lines 3-6 of section (4) on page 2 of Paper No. 121903. Applicants respectfully disagree and traverse.

Initially, Applicants note that the claims which were objected to have been cancelled. However, the language objected to is now recited in claims 132 (upon which claims 133-140 depend), 155 and 156. Thus, the following remarks pertain to claims 132-140, 155 and 156. It is noted, however, that claims 117-131 and 141-154 do not recite the language objected to and are, therefore, presumed to be allowable.

It is well understood that the specification need not provide written description support in exactly the same words as are used in the claims. In fact, the Federal Circuit has held that it is sufficient that the description conveys to one skilled in the art that Applicants had possession of the invention. For example, see *In re Wilder*, 736 F.2d 1516, 1520 (Fed. Cir. 1984):

> [i]t is not necessary that the claimed subject matter be described identically, but the disclosure originally filed must convey to those skilled in the art that applicant has invented the subject matter later claimed.

Moreover, the Federal Circuit has recently affirmed this view by holding "[i]f lack of literal support alone were enough to support a rejection under § 112, then the statement of *In re Lukach* "...that 'the invention claimed does not have to be described *in ipsis verbis* in order to satisfy the description requirement of § 112,' is empty verbiage." See *Union Oil Co. of California v. Atlantic Richfield Co. (Unocal)*, 208 F.3d 989, 1000 (Fed. Cir. 2000). Thus, there is no requirement that the claimed invention be described *verbatim* in the specification.

Applicants respectfully submit that the application as a whole clearly conveys a

role for the instant invention in stimulating the proliferation of myeloid cells. For example, the "Related Art" section of the instant application establishes that hematopoiesis, specifically myelopoiesis, is the field of science to which the instant invention is related. *See, e.g.*, page 1, line 14 through page 2, line 3 and also page 2, lines 9-11. In addition, the specification at page 5, lines 15-20 discloses that abnormal cell proliferation can be inhibited by suppressing the expression of HOIPS I, indicating that HOIPS I stimulates cell proliferation. The specification additionally teaches proliferative activity as a biological activity of the instant invention. *See* specification page 22, lines 16-17.

Further, the specification teaches that HOIPS I stimulates the proliferation of myelogenous leukemia cells:

> Thus, in one embodiment, the present invention provides a method for treating cell proliferative diseases, and in particular acute and chronic myelogenous leukemias, by inserting into an abnormally proliferating cell which expresses the HOIPS I gene a synthetic DNA or RNA construct of the present invention, wherein said DNA or RNA construct represses said expression.

See lines 23-27 on page 29 of the specification. Thus, the present invention provides a method for treating myelogenous leukemia by repressing expression of the HOIPS I gene. This disclosure clearly indicates that HOIPS I is involved in proliferation of myelogenous leukemia cells. Since myelogenous leukemia cells are congruous with myeloid cells (*see* definition of "myelogenous leukemia" from Merriam Webster's Medical Desk Dictionary, submitted herewith as Exhibit A), the specification discloses that HOIPS I stimulates the proliferation of myeloid cells.

Applicants respectfully submit that, based on the above cited support, the instant specification clearly discloses a role of HOIPS I in stimulating myeloid cell proliferation. Thus, Applicants' previous amendments to the claims to recite that the claimed proteins "stimulate the proliferation of myeloid cells" are fully supported by the specification as originally filed and, therefore, do not constitute new matter. As such, Applicants respectfully request that this objection be reconsidered and withdrawn.

II. Rejections Under 35 USC §112, first paragraph- written description

Claims 17-28, 30-36, 38-47, 49-53, 55-59, 61-74, 76-81, 83-90, 92-99, 101-107,

109-114 and 116 are rejected under 35 USC §112, first paragraph for allegedly lacking written description in the specification. Specifically, the Examiner states, "The claims are directed to an isolated protein comprising an amino acid sequence at least 90% identical to amino acid residues 1 to 142 of SEQ ID NO:2 and the claims have no limitations to the function of the protein... The claims must recite a specific, measurable activity such that one can recognize a polypeptide as that claimed, or a fragment thereof." *See* lines 5-7 of section (5) on page 3 and lines 8-10 on page 4 of Paper No. 121903. The Examiner adds, "In addition, the claims recite added material, which is not supported by the original disclosure. The independent claims for example, claim 17 recite 'wherein said protein stimulates the proliferation of myeloid cells' and there is no support for this in the instant specification." *See* lines 14-16 on page 4 of Paper No. 121903. Finally, the Examiner states that, "In view of the foregoing, at the time the application was filed, would not have taught one skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *See* lines 3-5 on page 5 of Paper No. 121903. Applicants respectfully disagree and traverse this rejection.

Claims 1-116 have been canceled. However it is worth noting that the Examiner's reasons for rejecting previous claims 17-28, 30-36, 38-47, 49-53, 55-59, 61-74, 76-81, 83-90, 92-99, 101-107, 109-114 and 116 apply only to claims that recite the "stimulates the proliferation of myeloid cells." Yet, previous claims 62-74, 76-81 and 83 did not recite such language. Accordingly, Applicants will address the rejection as it may apply to new claims that recite "stimulate proliferation of myeloid cells," namely new claims 132-140 and 155-156.

As discussed above, new claims 132-140 and 155-156 are fully supported by the specification as filed, for example, at line 4 on page 23 through line 9 on page 24, at lines 15-20 on page 5, lines 16-17 on page 22, and lines 23-27 on page 29. Regarding the written description requirement, the MPEP states, "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." *See* MPEP §2163 (I) (B). Applicants assert that the instant specification clearly conveys to the skilled artisan that Applicants, at the earliest effective filing date of the instant application, were in possession of the claimed invention. Applicants submit that claims 132-140 and 155-156 do, in fact, recite or depend from a claim that recites a specific,

measurable activity, that is, to stimulate the proliferation of myeloid cells.

Regarding the Examiner's allegation that the instant application would not have taught the skilled artisan how to make and use the claimed invention, Applicants submit that such a prerequisite is not the legal standard for satisfying the written description requirement, but rather, is relevant to enablement. Regardless, Applicants submit that the instant application clearly teaches one skilled in the art how to make and use the claimed invention.

In view of the above remarks, Applicants submit that the claimed invention is fully disclosed and defined by the instant specification. Accordingly, Applicants respectfully request that this rejection under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: 3-23-04

Respectfully submitted,

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MJH/LJH/KM/lcc/ba

[1]**myd·ri·at·ic** \ˌmid-rē-ˈat-ik\ *adj* : causing or involving dilation of the pupil of the eye

[2]**mydriatic** *n* : a drug that produces dilation of the pupil of the eye

my·ec·to·my \mī-ˈek-tə-mē\ *n, pl* **-mies** : surgical excision of part of a muscle

my·el·en·ceph·a·lon \ˌmī-ə-len-ˈsef-ə-ˌlän, -lən\ *n* : the posterior part of the developing vertebrate hindbrain or the corresponding part of the adult brain composed of the medulla oblongata — **my·el·en·ce·phal·ic** \-ˌlen(t)-sə-ˈfal-ik\ *adj*

my·el·ic \mī-ˈel-ik\ *adj* : of or relating to the spinal cord

my·e·lin \ˈmī-ə-lən\ *n* : a soft white somewhat fatty material that forms a thick myelin sheath about the protoplasmic core of a myelinated nerve fiber — **my·e·lin·ic** \ˌmī-ə-ˈlin-ik\ *adj*

my·e·lin·at·ed \ˈmī-ə-lə-ˌnāt-əd\ *adj* : having a myelin sheath (~ nerve fibers)

my·e·li·na·tion \ˌmī-ə-lə-ˈnā-shən\ *n* **1** : the process of acquiring a myelin sheath **2** : the condition of being myelinated

myelin basic protein *n* : a protein that is a constituent of myelin, that causes experimental allergic encephalomyelitis when injected into laboratory animals, and that prob. acts as an autoantigen in individuals affected with multiple sclerosis — abbr. *MBP*

my·e·lin·iza·tion *also Brit* **my·e·lin·isa·tion** \ˌmī-ə-ˌlin-ə-ˈzā-shən\ *n* : MYELINATION

my·e·li·noc·la·sis \ˌmī-ə-lə-ˈnäk-lə-səs\ *n, pl* **-la·ses** \-ˌsēz\ : the process of destruction of myelin leading to demyelination — **my·e·li·no·clas·tic** \-ˌlin-ə-ˈklast-ik\ *adj*

my·e·li·nol·y·sis \-ˈnäl-ə-səs\ *n, pl* **-y·ses** \-ˌsēz\ : DEMYELINATION — see CENTRAL PONTINE MYELINOLYSIS

my·e·li·no·tox·ic \ˌmī-ə-ˌlin-ə-ˈtäk-sik\ *adj* : destructive of myelin (a substance that is ~ in vitro)

myelin sheath *n* : a layer of myelin surrounding some nerve fibers — called also *medullary sheath*

my·e·li·tis \ˌmī-ə-ˈlīt-əs\ *n, pl* **my·e·lit·i·des** \-ˈlit-ə-ˌdēz\ : inflammation of the spinal cord or of the bone marrow — **my·e·lit·ic** \-ˈlit-ik\ *adj*

my·e·lo·ar·chi·tec·ton·ic \ˌmī-ə-lō-ˌär-kə-ˌtek-ˈtän-ik\ *adj* : of or relating to myeloarchitectonics

my·e·lo·ar·chi·tec·ton·ics \-iks\ *n pl but sing in constr* : cytological architectonics of the brain, spinal cord, or bone marrow

my·e·lo·blast \ˈmī-ə-lə-ˌblast\ *n* : a large mononuclear nongranular bone-marrow cell; *esp* : one that is a precursor of a myelocyte — compare LEUKOBLAST — **my·e·lo·blas·tic** \ˌmī-ə-lə-ˈblas-tik\ *adj*

my·e·lo·blas·te·mia *or chiefly Brit* **my·e·lo·blas·tae·mia** \ˌmī-ə-lō-blas-ˈtē-mē-ə\ *n* : the presence of myeloblasts in the circulating blood (as in myelogenous leukemia)

myeloblastic leukemia *n* : MYELOGENOUS LEUKEMIA

my·e·lo·blas·to·ma \-blas-ˈtō-mə\ *n, pl* **-mas** *or* **-ma·ta** \-mət-ə\ : a myeloma consisting of myeloblasts

my·e·lo·blas·to·sis \-blas-ˈtō-səs\ *n, pl* **-to·ses** \-ˌsēz\ : the presence of an abnormally large number of myeloblasts in the tissues, organs, or circulating blood

my·e·lo·cele \ˈmī-ə-lə-ˌsēl\ *n* : spina bifida in which the neural tissue of the spinal cord is exposed — compare MYELOMENINGOCELE

my·e·lo·coele \ˈmī-ə-lə-ˌsēl\ *n* : the central canal of the spinal cord

my·e·lo·cyte \ˈmī-ə-lə-ˌsīt\ *n* : a bone-marrow cell; *esp* : a motile cell with cytoplasmic granules that gives rise to the blood granulocytes and occurs abnormally in the circulating blood (as in myelogenous leukemia) — **my·e·lo·cyt·ic** \ˌmī-ə-lə-ˈsit-ik\ *adj*

myelocytic leukemia *n* : MYELOGENOUS LEUKEMIA

my·e·lo·cy·to·ma \ˌmī-ə-lō-sī-ˈtō-mə\ *n, pl* **-mas** *or* **-ma·ta** \-mət-ə\ : a tumor esp. of fowl in which the typical cellular element is a myelocyte or a cell of similar differentiation

my·e·lo·cy·to·sis \-sī-ˈtō-səs\ *n, pl* **-to·ses** \-ˌsēz\ : the presence of excess numbers of myelocytes esp. in the blood or bone marrow

my·e·lo·dys·pla·sia \-dis-ˈplā-zh(ē-)ə\ *n* : a developmental anomaly of the spinal cord — **my·e·lo·dys·plas·tic** \-ˈplas-tik\ *adj*

my·e·lo·fi·bro·sis \ˌmī-ə-lō-fī-ˈbrō-səs\ *n, pl* **-bro·ses** \-ˌsēz\ : an anemic condition in which bone marrow becomes fibrotic and the liver and spleen usu. exhibit a development of blood-cell precursors — **my·e·lo·fi·brot·ic** \-ˈbrät-ik\ *adj*

my·e·log·e·nous \ˌmī-ə-ˈläj-ə-nəs\ *also* **my·e·lo·gen·ic** \ˌmī-ə-lə-ˈjen-ik\ *adj* : of, relating to, originating in, or produced by the bone marrow (~ sarcoma)

myelogenous leukemia *n* : leukemia characterized by proliferation of myeloid tissue (as of the bone marrow and spleen) and an abnormal increase in the number of granulocytes, myelocytes, and myeloblasts in the circulating blood — called also *granulocytic leukemia, myeloblastic leukemia, myelocytic leukemia, myeloid leukemia;* see ACUTE MYELOGENOUS LEUKEMIA, ACUTE NONLYMPHOCYTIC LEUKEMIA, CHRONIC MYELOGENOUS LEUKEMIA

my·e·lo·gram \ˈmī-ə-lə-ˌgram\ *n* **1** : a differential study of the cellular elements present in bone marrow usu. made on material obtained by sternal biopsy **2** : a roentgenogram of the spinal cord made by myelography

my·e·lo·graph·ic \ˌmī-ə-lə-ˈgraf-ik\ *adj* : of, relating to, or made by means of a myelogram or myelography — **my·e·lo·graph·i·cal·ly** \-i-k(ə-)lē\ *adv*

my·e·log·ra·phy \ˌmī-ə-ˈläg-rə-fē\ *n, pl* **-phies** : roentgenographic visualization of the spinal cord after injection of a contrast medium into the spinal subarachnoid space

my·e·loid \ˈmī-ə-ˌlȯid\ *adj* **1** : of or relating to the spinal cord **2** : of, relating to, or resembling bone marrow

myeloid leukemia *n* : MYELOGENOUS LEUKEMIA

my·e·lo·li·po·ma \ˌmī-ə-lō-lī-ˈpō-mə, -lip-ˈō-mə\ *n, pl* **-mas** *or* **-ma·ta** \-mət-ə\ : a benign tumor esp. of the adrenal glands that consists of fat and hematopoietic tissue

my·e·lo·ma \ˌmī-ə-ˈlō-mə\ *n, pl* **-mas** *or* **-ma·ta** \-mət-ə\ : a primary tumor of the bone marrow formed of any one of the bone-marrow cells (as myelocytes or plasma cells) and usu. involving several different bones at the same time — see MULTIPLE MYELOMA

my·e·lo·ma·to·sis \ˌmī-ə-lō-mə-ˈtō-səs\ *n, pl* **-to·ses** \-ˌsēz\ : MULTIPLE MYELOMA

my·e·lo·ma·tous \ˌmī-ə-ˈlō-mət-əs, -ˈläm-ət-əs\ *adj* : of or relating to a myeloma or to myelomatosis

my·e·lo·me·nin·go·cele \ˌmī-ə-lō-mə-ˈniŋ-gə-ˌsēl, -mə-ˈnin-jə-\ *n* : spina bifida in which neural tissue and the investing meninges protrude from the spinal column forming a sac under the skin — compare MYELOCELE

my·e·lo·mono·cyte \-ˈmän-ə-ˌsīt\ *n* : a myelomonocytic blood cell

my·e·lo·mono·cyt·ic \-ˌmän-ə-ˈsit-ik\ *adj* : relating to or being a blood cell that has the characteristics of both monocytes and granulocytes

myelomonocytic leukemia *n* : a kind of monocytic leukemia in which the cells resemble granulocytes

my·e·lo·path·ic \-ˈpath-ik\ *adj* : of or relating to a myelopathy : resulting from abnormality of the spinal cord or the bone marrow (~ anemia)

my·e·lop·a·thy \ˌmī-ə-ˈläp-ə-thē\ *n, pl* **-thies** : any disease or disorder of the spinal cord or bone marrow

my·e·lo·per·ox·i·dase \ˌmī-ə-lō-pə-ˈräk-sə-ˌdās, -ˌdāz\ *n* : a green peroxidase of phagocytic cells (as neutrophils and monocytes) that is held to assist in bactericidal activity by catalyzing the oxidation of ionic halogen to free halogen

my·e·lo·phthi·sic anemia \-ˈtiz-ik-, -ˈtī-sik-\ *n* : anemia in which the blood-forming elements of the bone marrow are unable to reproduce normal blood cells and which is commonly caused by specific toxins or by overgrowth of tumor cells

my·e·lo·plax \ˈmī-ə-lə-ˌplaks, mī-ˈel-ə-\ *n* : any of the large multinucleate cells in bone marrow

my·e·lo·poi·e·sis \ˌmī-ə-lō-(ˌ)pȯi-ˈē-səs\ *n, pl* **-poi·e·ses** \-ˌsēz\ **1** : production of marrow or marrow cells **2** : production of blood cells in b
Blood granulocytes

my·e·lo·poi·et·ic \-(ˌ)pȯi-ˈe
clopoiesis

my·e·lo·pro·lif·er·a·tive \
adj : of, relating to, or
marked by excessive pro
ments and esp. blood cell

my·e·lo·ra·dic·u·li·tis \-rə-
mation of the spinal cord

my·e·lo·scle·ro·sis \-sklə-ˈr
sclerosis of the bone mar

my·e·lo·sis \ˌmī-ə-ˈlō-səs\ *n,*
liferation of marrow tissue
distribution typical of myel
ENOUS LEUKEMIA

my·e·lo·spon·gi·um \ˌmī-ə-l
a network in the embryo
rived from the spongioblast
glia

my·e·lo·sup·pres·sion \-sə-ˈp
bone marrow's production

my·e·lo·sup·pres·sive \-sə-ˈp
pression (~ chemotherapy)

my·e·lot·o·my \ˌmī-ə-ˈlät-ə-
sion of the spinal cord; *esp*
bers at the midline of the sp
fibers for the relief of intrac

my·e·lo·tox·ic \ˌmī-ə-lō-ˈtäk-
marrow or any of its elemen

te·ly \-täk-ˈsis-ət-ē\ *n, pl* **-t**

my·en·ter·ic \ˌmī-ən-ˈter-ik\
cular coat of the intestinal v

myenteric plexus *n* : a netwo
between the longitudinal and
intestine — called also *Auerb*
NER'S PLEXUS

myenteric plexus of Auerbac

myenteric reflex *n* : a reflex th
of peristalsis moving along t
contraction of the digestive t
low the place where it is st
mass of food

my·en·ter·on \mī-ˈen-tə-ˌrän\
intestine

my·ia·sis \mī-ˈī-ə-səs, mē-\ *n,*
tion with fly maggots

My·lan·ta \mī-ˈlan-tə\ *tradem*
antiflatulent preparation of a
sium hydroxide, and simethic

My·le·ran \ˈmil-ə-ˌran\ *tradem*
of busulfan

My·li·con \ˈmī-lə-ˌkän\ *tradem*
of simethicone

my·lo·hy·oid \ˌmī-lō-ˈhī-ˌȯid\
ing the mylohyoid muscle

mylohyoid *n* : MYLOHYOID MUSC

my·lo·hy·oi·de·us \-hī-ˈȯid-ē-əs
OID MUSCLE

mylohyoid line *n* : a ridge on t
the lower jaw extending from t
of the bone in front to the last m
attachment to the mylohyoid

mylohyoid muscle *n* : a flat tria
of the mouth that is located ab
digastric muscle, extends fro
mandible to the hyoid bone, a
posite side forms the floor of t
hyoid, mylohyoideus

mylohyoid ridge *n* : MYLOHYOID

myo·blast \ˈmī-ə-ˌblast\ *n* : an u
of giving rise to muscle cells

myo·blas·to·ma \ˌmī-ə-(ˌ)blas-ˈ

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